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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,445

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Shawn DeFrees

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EXAMINER

LEWIS, PATRICK T

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

11/04/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,445	<b>Applicant(s)</b> DEFREES, SHAWN	
	<b>Examiner</b> Patrick T. Lewis	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 23-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-17, 22, 39 and 40 is/are rejected.
- 7) ☒ Claim(s) 18-21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group II (claims 12-22 and 39-40) in the reply filed on September 11, 2009 is acknowledged.
2. Claims 1-11 and 23-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 11, 2009.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 12-15, 22 and 39-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 fails to particularly set forth the metes and bounds of R<sup>14</sup>. The phrases "reactive functional group" and "a group that is linked to a carrier molecule" render the claim indefinite. Said phrases do not convey a chemical structure. There is nothing inherently wrong with defining some part of an invention in functional terms; however, a functional limitation must be evaluated and considered, just like any other limitation of

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the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used.

***Claim Rejections - 35 USC § 102***

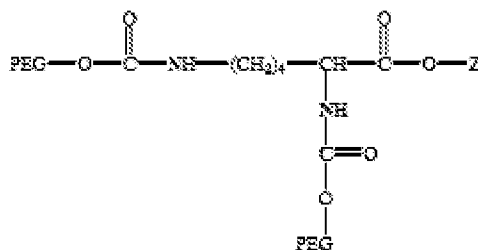
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 12-13, 16-17, 22 and 39-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kozlowski US 6,376,604.

Kozlowski teaches the reaction of BTC esters of water-soluble and non-peptide polymers with amino acids to form amino acid derivatives (column 6, line 43 to column 7, line 23). In one embodiment, PEG-BTC esters are reacted with lysine to form a polymeric lysine derivative. For example, one such lysine derivative is a doubly PEGylated lysine, wherein the two PEGs are linked to the lysine amines by carbamate bonds, as show below



Wherein PEG is poly(ethylene glycol) and Z is selected from the group consisting of H, N-succinimidyl, or 1-benzotrizolyl. The BTC esters of water-soluble and non-peptidic

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polymers can also be reacted with biologically active agents to form biologically active polymer conjugates. Examples of biologically active agents include peptides, proteins, enzymes, small molecule drugs, dyes, lipids, nucleosides, oligonucleotides, cells, viruses, liposomes, microparticles and micelles. It is believed that polymer derivatives prepared according to the invention exhibit higher quality because degradation of the polymer backbone caused by phosgene is avoided. Further, since the method of the invention requires only one step and fewer reactants, process efficiency is enhanced and cost is reduced. PEG having a molecular weight of from about 200 Daltons to about 100,000 Daltons is particularly useful as the polymer backbone (column 4, lines 24-29).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kozlowski as applied to claims 12-13, 16-17, 22 and 39-40 above, and further in view of Sheridan J. Chem. Inf. Comput. Sci. (2002), Vol. 42, pages 103-108 (Sheridan).

Kozlowski differs from the instantly claimed invention in the Kozlowski does not teach  $s = 1$  (homolog) or  $A = S$  (bioisostere); however, these deficiencies would have been obvious to one of ordinary skill in the art at the time of the invention in view of Sheridan.

Sheridan teaches that bioisosterism is the concept that a chemical group in a biologically active compound can be replaced with another such that the new molecule retains the biological activity (pages 103 and 105). The presumption is that the groups to be substituted are similar in some important physical property. The top 10 fragment-pairs, plus some other interesting ones are shown in Figure 5. Many of these seem to be "classical" replacements in medicinal chemistry. The most common replacement (labeled A1 in Figure 5) is the replacement of C with N in an aromatic ring. The next most common (A2) is  $-O- \leftrightarrow -S-$ . This can occur in aliphatic chains, aliphatic rings, and aromatic rings.

A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. "An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties." In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979).

### ***Conclusion***

10. Claims 1-40 are pending. Claims 1-11 and 23-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claims 12-17, 22 and 39-40 are rejected. Claims 18-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No claims are allowed.

### ***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on Monday - Friday 10 am to 3 pm (Maxi Flex).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patrick T. Lewis/  
Primary Examiner, Art Unit 1623

/PL/